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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/717,993 | 11/20/2003 | Chi Li Liu | 2027.631000 | 7643 |
| 23720 7590 08/29/2007 WILLIAMS, MORGAN & AMERSON 10333 RICHMOND, SUITE 1100 HOUSTON, TX 77042 | | | EXAMINER MEAH, MOHAMMAD Y | |
| | | | ART UNIT 1652 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-----------------------------------|--|
| Office Action Summary | Application No. 10/717,993 | Applicant(s) LIU ET AL. | |
| | Examiner Mohammad Meah | Art Unit 1652 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23, 102, 129 and 130 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23, 102, 129-130 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-23 and 102 were examined in the previous action. With supplemental amendment of this application, the applicant, on date 06/13/07 amended claims 1, 102 and added claims 129-130.

Claim Rejections

35 U.S.C 112

35 U.S.C. 112, second paragraph

Rejection of claims 1, 2-23 (dependent on claim 1) and 102 under U.S.C. 112, 2nd paragraph are withdrawn after amendment of the claims.

Written Description requirement

Rejections of claims 1-10, 12-20, 22-23, 102 under 35 U.S.C. 112, first paragraph Written Description requirement is withdrawn after amendment of the claims.

III. Enablement requirement

Rejections of claims 1-10, 12-20, 22-23, 102 under 35 U.S.C. 112, first paragraph . Enablement requirement is withdrawn after amendment of the claims.

CLAIM Rejection - 35 U.S.C 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the

requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Rejection of claims 1-9, 12-23, 102 under 35 U.S.C. 102(e) as being anticipated by Hause et al. (US 2003/0228671) for the reasons explained in the prior action, is maintained.

Hause et al. teach various recombinant yeasts strains (*Kluyvermyces*, *Candida*, etc) which produce high yield of lactic acid (95 gm/ 100 gram of glucose) at low pH (below ~2.3) in a culture medium containing at least among others glucose and one nitrogen source, wherein said yeast expresses (through integration to yeast chromosome or through plasmid) various exogenous LDH genes including from *Lactobacillus plantarum*. They also teach the production and isolation of lactic acid at high yield (i.e. 95% or 95gm/ gm of sugar used) without producing any pyruvate at low pH (below ~ 2.3) using nitrogen as nutrient and carbohydrate (glucose, etc) as only carbon source.

Applicants argument that Hause et al. do not teach every element of the instant claims (LDH gene from *Lactobacillus plantarum*, bovine, *Lactobacillus casei*, *Bacillus megaterium*, *Rhizopus oryzae*, or *Bacillus stearothermophilus*; AT yeast strain, capable to grown in minimal media, produce less than 1 ppm ethanol) is not found to be true as explained in prior office action rejection and discuss below: Hause et al. teach **AT yeast** strain expressing exogenous LDH gene from ***Lactobacillus plantarum***. Hause et al use yeast strains , such as *Kluyveromyces Marxianus* , for the production of lactate at **pH 2.3** wherein **no ethanol is produced**. Applicant's

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argument, that Hause et al. **does not teach minimal medium and aerobic condition in the process of production of Lactic acid is also not true.** Although Hause et al. used variety of harvesting media they also teach a media with only carbohydrate as carbon source and nutrients (nitrogen, minerals etc (page 0075) and also teach fermentation condition with controlled oxygen (aerobic) supply. Applicants argument that Hause et al. does not use parent yeast strain for expression of LDH gene is not true because they use yeast strain like *Kluyveromyces Marxianus* to expresses (through integration to yeast chromosome or through plasmid) various exogenous LDH genes including *from Lactobacillus plantarum*.

Rejection of claim 10 under 35 U.S.C. 102(b) as being anticipated by Hause et al. (US 2003/0228671) is withdrawn after applicants argument.

Claims 1-10, 12-23, 102 are rejected under 35 U.S.C. 102(e) as being anticipated by Rajgarhia et al. (US 2004/0029238). Rajgarhia et al. teach various recombinant yeast (*Sachharomyces, Kluyvermyces, Candida, etc*) strains expressing (through integration to yeast chromosome or through plasmid) various exogenous LDH genes including *from K. lactis* or *Rhizopus oryzae* (paragrgph 92). which capable of growing in **minimal medium** of cell culture. Rajgarhia et al. also teach method of production of lactic acid (95 gm/ 100 gram of glucose) **wherein no ethanol** is produced using said yeast strain comprising fermentation step at **low pH (below ~2.3) in minimal medium**. Applicants argument that Rajgarhia et al. do not teach every element of the instant claims (LDH gene from *Lactobacillus plantarum, bovine, Lactobacillus casei, Bacillus megaterium, Rhizopus oryzae, or Bacillus*

stearothermophilus; AT yeast strain, capable to grown in minimal media, produce less than 1 ppm ethanol) is not found to be true as explained in prior rejection and above (bold faced) because Rajgarhia et al. express parent yeast strain like *Saccharomyces*, *Kluyvermyces*, *Candida* with various exogenous LDH genes including from *K. lactis* or *Rhizopus oryzae* and said recombinant AT strain produce lactic acid (95 gm/ 100 gram of glucose) wherein **no ethanol** is produced using said yeast strain comprising fermentation step at **low pH (bellow ~2.3)** in **minimal medium**.

CLAIM Rejection - 35 U.S.C 103a

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 129-130 are rejected under 35 U.S.C. 103(a) by as being obvious over Rajgarhia et al. (US 2004/0029238) in view of Barnett et al. (Yeasts: characterization and identification 2nd edition, Cambridge University press ISBN 052135056, page 20-28 from applicant reference) . Rajgarhia et al. teach various recombinant yeast (

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Sachharomyces, *Kluyvermyces*, *Candida*, etc) strains expressing (through integration to yeast chromosome or through plasmid) various exogenous LDH genes including from *K. lactis* or *Rhizopus oryzae* (paragrgph 92). which capable of growing in **minimal medium** of cell culture. Rajgarhia et al. also teach method of production of lactic acid (95 gm/ 100 gram of glucose) **wherein no ethanol** is produced using said yeast strain comprising fermentation step at **low pH (below ~2.3) in minimal medium**. However Rajgarhia et al. do not teach a method of selection of AT yeast strain.

It is well known in art how to grow yeast and make a selection of specific strain (ref: Barnett et al.) . Barnett et al teach how to grow yeast strain at different media and pH and select the specific strain. One in knowledgeable in prior art is **motivated** to select Rajgarhia et al's yeast strain that capable to grow at low pH and minimal media and grow it more lower pH. As such it would have been obvious to one of ordinary skill in the art to grow Rajgarhia et al's yeast (*Sachharomyces*, *Kluyvermyces*, *Candida*, etc) strains expressing (through integration to yeast chromosome or through plasmid) various exogenous LDH genes including from *K. lactis* or *Rhizopus oryzae* which is capable of growing in **minimal medium** of cell culture and grow it different media and pH and make a selection of AT yeast strain as taught by Barnett et al.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This action is final because applicants' edition of the new claims 129-130, after non-final action necessitates the above 103 rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax

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phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mohammad Younus Meah, PhD

Examiner, Art Unit 1652

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